K041215

SEP - 9 2004

OTTO BOCK®

QUALITY FOR LIFE

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	OTTO BOCK HealthCare LP
2.	*Address:*	Two Carlson Parkway N., Suite 100 Minneapolis, MN 55447-4467
3.	*Telephone:*	763-489-5153
4.	*Contact Person:*	Shelley Stockman
5.	*Date Prepared:*	September 4, 2004
6.	*Registration Number:*	2182293

B. Device

1.	*Name:*	Cranial Helmet
2.	*Trade Name:*	Cranial Helmet
3.	*Common Name:*	Cranial Orthosis
4.	*Classification Name:*	Cranial Orthosis
5.	*Product Code:*	MVA
6.	*Class:*	II
7.	*Regulation Number:*	882.5970

C. Identification of Legally Marketed Devices

1. *Name:* Fit Well's P.A.P. Orthosis
2. *K Number:* K012804
3. *Date Cleared:* January 17, 2002

D. Description of the Device

The Cranial Helmet is a cranial orthosis custom fabricated to apply pressure to the prominent regions of an infant's cranium to improve cranial symmetry and shape.

The Cranial Helmet is comprised of the same materials as the P.A.P. Orthosis (K012804). It is not packaged for sale, as it is custom fabricated. It will be fitted to the infant at the time of delivery. The Cranial Helmet has no accessories, and no options are available for the infant or the caregiver (parent).

Caregivers are instructed as to: wear, care, cautions, and risks.

The transparent thermoplastic is Surlyn which varies in thickness from 1/8 inch to 3/8 inch depending upon the desired characteristics. The helmet is fabricated from a cast taken of an infant's head. There are no standard sizes, models, variances, etc.

A polyurethane foam strip is applied to the posterior border at the base of the occipital to provide suspension and anti-rotation. Each Cranial Helmet is fastened with a Velcro strap.

Each infant with a Cranial Helmet must be under the care of a physician. The helmet is a Prescription Device.

E. Intended Use Statement

The Cranial Helmet (cranial orthosis) is a device that is intended for medical purposes to apply pressure to the prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with a diagnosis of moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

F. Technological Characteristics Summary

Similarities between both Cranial Orthosis' are the following

- Identical Indications for Use
- Same Materials (Surlyn, Polyurethane, Silicone and Velcro)
- Custom Fabrication
- Function – Same
- Purpose – Same
- Shape
- Diagnosis
- Prescription Devices
- Follow FDA Special Controls

Differences are the P.A.P. is fabricated by Fit-Well Prosthetic and Orthotic Center in Salt Lake City, Utah and the OTTO BOCK Cranial Helmet is fabricated at our technical center in Minneapolis, Minnesota.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2004

OTTO Bock HealthCare LP
c/o Mr. William Jackson
W.F. Jackson Associates, Limited
2247 Jennifer Lane
St. Paul, Minnesota 55109-2851

Re: K041215
Trade/Device Name: Cranial Orthosis
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: August 6, 2004
Received: August 17, 2004

Dear Mr. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number : K04215

Device Name: Cranial Helmet

Indications for Use:

- Prescription Device
- The Cranial Helmet (cranial orthosis) is a device that is intended for medical purposes to apply pressure to the prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with a diagnosis of moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.
- Contraindications: Infants with Synostosis or Hydrocephalus

Prescription Use _X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041215